IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BRENDA SMITH, Individually and as Administratix of the Estate of RICKY SMITH	:	**No.** 3:16-CV-1264
Plaintiffs	:	
v.	:	
SAMIR B. PANCHOLY, M.D. FACC, FSCAI; SAMIR B. PANCHOLY, LLC; NORTH PENN CARDIOVASCULAR SPECIALISTS; HAITHAM ABUGHNIA, M.D.; AND BIOTRONIK, INC.	:	**JURY TRIAL DEMANDED**
Defendants.	:	

NOTICE OF REMOVAL

TO THE HONORABLE JUDGES OF THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF PENNSYLVANIA:

Defendant, Biotronik, Inc., by and through its counsel, Marshall Dennehey Warner Coleman & Goggin, pursuant to 28 U.S.C. §§ 1331, 1441 and 1446, files this Notice of Removal of a certain action pending in the Lackawanna County Court of Common Pleas, (hereinafter "State Court"), and in support thereof states as follows:

1. Biotronik, Inc. is named as a defendant in the action entitled *Smith v. Pancholy et al.*, 2016-CV-01789, pending in State Court. A true and correct copy of plaintiff's Complaint is attached hereto as Exhibit "A."

2. Plaintiffs commenced this action by filing a Complaint on or about May 24, 2016, in State Court.

3. Biotronik was served with the Complaint on May 31, 2016.

4. Samir B. Pancholy, M.D., Samir B. Pancholy, LLC, Haitham Abughnia, M.D., and North Penn Cardiovascular Specialists are also named as defendants in the Complaint. All defendants consent to removal of this action to this Court pursuant to 28 U.S.C § 1446(a). See Affidavit of Consent, attached hereto as Exhibit "B."

5. Under 28 U.S.C. § 1446(b), this Notice of Removal must be filed within 30 days of service of the Complaint upon Biotronik. Because Biotronik is filing this Notice on June 23, 2016, removal is timely.

6. Concurrent with the filing of this Notice, Biotronik is serving this Notice on plaintiffs' counsel and filing a copy of the Notice with the Court of Common Pleas of Lackawanna County, Pennsylvania. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1441(a) because the United States District Court for the Middle District of Pennsylvania is the federal judicial district

embracing the Lackawanna County Court of Common Pleas, where this action was originally filed.

7. By filing a Notice of Removal in this matter, Biotronik does not waive its rights to object to service of process, the sufficiency of process, jurisdiction over the person, or venue. Biotronik, as well, specifically reserves its rights to assert any defenses and/or objections to which it may be entitled.

8. As shown below, this case is removable to federal court based on the federal question jurisdiction pursuant to 28 U.S.C. § 1331.

9. In the alternative, Biotronik requests that this Court exercise its power pursuant to Rule 21 of the Federal Rules of Civil Procedure to sever Defendants Samir B. Pancholy, M.D., Samir B. Pancholy, LLC, Haitham Abughnia, M.D., and North Penn Cardiovascular Specialists (collectively and hereinafter the "Medical Defendants"), in order to perfect diversity jurisdiction over Biotronik. See, e.g., See Newman-Green, Inc. v. Alfonzo-Larrain, 490 U.S. 826, 832-38 (1989) (holding that a federal court may, pursuant to Rule 21, sever non-diverse, dispensable parties to retain diversity jurisdiction); Meritcare Inc. v. St. Paul Mercury Ins. Co., 166 F.3d 214, 222-23 (3d Cir. 1999) (same).

FEDERAL QUESTION JURISDICTION

10. Under 28 U.S.C. § 1331, the federal district courts "have original jurisdiction of all civil actions arising under the Constitution, laws, or treatises of

the United States." 28 U.S.C. § 1331; see also 28 U.S.C. § 1441(a) ("[A]ny civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending.")

11. In the Complaint, plaintiffs allege that Mr. Smith was injured by a Biotronik Implantable Cardioverter-Defibrillator ("ICD") model Lumax 740 HF-T. See Exhibit A. Plaintiffs also make allegations regarding Biotronik implantable cardioverter defibrillator leads (hereinafter "leads"), model Linox SD. See id.

12. Federal regulation of medical devices is governed by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c et seq. See Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008).

13. The MDA establishes three (3) classes of stringent federal oversight:

> Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight[.]" ... Class II, which includes such devices as powered wheelchairs and surgical drapes, is subject in addition to 'special controls' such as performance standards and postmarket surveillance measures[.] ... The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators[.]

Id. at 316-17 (emphasis added).

14. Only devices that support or sustain human life or present a potential unreasonable risk of illness or injury are designated Class III devices. 21 U.S.C. § 360c(a)(1)(C)(ii).

15. Class III devices must go through "a rigorous regime of premarket approval" before they may be brought to market. Id. at 317.

16. The Biotronik ICD and leads are Class III medical devices whose design, manufacturing method, labeling, and instructions for installation and operation, inter alia, were specifically approved by the Food and Drug Administration ("FDA") pursuant to the agency's Premarket Approval ("PMA") process.[1]

17. The PMA process for Class III devices is the most exacting form of FDA review. See, e.g., Riegel, 552 U.S. at 317-20 (explaining rigorous and lengthy process for premarket approval of Class III devices).

18. Section 360k(a) of the MDA expressly preempts any state-law claim that would impose a requirement that is "different from, or in addition to, any

[1] The Class III classification of these medical devices are a matter of public record accessible in the FDA's public database online at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Thus, this Court may take judicial notice of the fact of Biotronik's premarket approval, as the FDA website is a database maintained by it in the normal course of its business and reflects final agency action. See Fed. R. Evid. 201; see also, e.g., Desai v. Sorin CRM USA, Inc., 2013 U.S. Dist. LEXIS 5795, *10, 2013 WL 163298 (D.N.J. Jan. 15, 2013) (holding that courts take judicial notice of the FDA's website and the fact that the medical device received premarket approval); Starks v. Coloplast Corp., 2014 U.S. Dist. LEXIS 19611, *3 n.3 (E.D. Pa. Feb. 13, 2014) (holding that courts take judicial notice of documents that are matters of public record such as FDA reports published on the FDA website). If this Honorable Court so requires, Defendant Biotronik will provide this Court with the necessary records demonstrating Class III PMA classification.

requirement applicable . . . to the device" under federal law and imposed by the FDA. 21 U.S.C. § 360k(a); Riegel, 552 U.S. at 321–28. In other words, Congress expressly preempted state-law tort claims challenging the design, manufacture, or labeling of a medical device previously approved by the FDA via the PMA process. The United States Supreme Court reinforced Congress' express preemption in its recent decision in Riegel.

19. In the Complaint, plaintiffs set forth products liability claims against Biotronik, including manufacturing defects; design defects; malfunctioning of the medical devices; defective labeling, instructions, and/or warnings; and breach of express and implied warranty. See Exhibit A, at Counts V-VIII.

20. While plaintiffs' claims against Biotronik appear to be pleaded under state law, each claim is predicated on alleged breaches of duties imposed by **federal law** and challenges the safety and effectiveness of a device subject to pervasive federal regulation and stringent administrative oversight. Notably, plaintiffs cannot state a claim, nor can they prevail in this matter, against Biotronik without setting forth a causally-linked violation of relevant FDA requirements. Riegel, 552 U.S. at 330. In other words, demonstrating a violation of federal law is critical and indispensable to plaintiffs' claims and burden of proof against Biotronik.

21. The threshold inquiry in determining whether a claim "arises under federal law" — and thus is removable — must be determined by reference to the well-pleaded complaint rule. Merrell Dow Pharmaceuticals, Inc. v. Thompson, 478 U.S. 804, 808 (1986).

22. In Franchise Tax Bd. v. Constr. Laborers Vacation Trust, 463 U.S. 1 (1983), the Supreme Court identified two situations where federal jurisdiction could be available even though the plaintiff's claim in state court is nominally based on state law, i.e., (1) when "it appears that some substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims" or (2) when it appears that the plaintiff's claim "is 'really' one of federal law." Id. at 13; see also Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg., 545 U.S. 308, 312 (2005) (holding that a claim may arise under federal law, and thus invoke federal-question jurisdiction either (1) where plaintiff pleads a cause of action created by federal law or (2) plaintiff's state-law claims implicate significant federal issues.)

23. The second form of federal-question jurisdiction "captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." Grable, 545 U.S. at 312.

24. The Supreme Court has "disclaimed the adoption of any bright-line rule" when evaluating whether a federal statute creates a substantial federal interest giving rise to federal-question jurisdiction over claims pleaded under state law. Id. at 317. "Instead, the question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities." Id. at 314.

25. By enacting the MDA § 360k(a), Congress expressly established and bolstered a substantial federal interest, particularly as it relates to the regulation of Class III PMA medical devices. The Supreme Court explicitly reinforced such federal interests and express preemption in Riegel. As the Supreme Court explained in Riegel, the very purpose of the MDA was to "swe[ep] back some state obligations and impose[] a regime of detailed federal oversight." Riegel, 552 U.S. at 316.

26. Due to the facts that Congress entrusted the regulation of medical devices to the exclusive authority of the FDA and removed it from the hands of state legislatures, Congress consequently intended the litigation of claims innovative Class III PMA-medical devices — the most complex devices subject to the most stringent and rigorous federal oversight — to be removable from state courts. In other words, by imposing a regime of such detailed federal oversight,

Congress intended that litigation proceed in federal court so that the federal judiciary may decide such severely regulated federal matters. See, e.g., id., at 316-30.

27. By filing a Complaint for an injury allegedly caused by a Class III PMA medical device, plaintiffs must be alleging conduct that violated the FDA. Otherwise, plaintiffs' claims will be expressly preempted by § 360k(a). See id. at 330 (explaining that § 360k does not prevent a state from providing a damages remedy for claims premised on a violation of FDA regulations). Either way, a federal duty and requirement is inevitably at issue in this case and is, in fact, a required element of plaintiffs' claims against Biotronik. Thus, the disposition of such claims certainly "implicate significant federal issues" and "turn on substantial questions of federal law." See Grable, 545 U.S. at 312.

28. The federal interest in this case is undoubtedly substantial, and the claims asserted are likely to be dispositive based on Riegel and the express preemption of § 360k(a) as it pertains to Class III PMA medical devices. The substantiality of federal interest in this case is further evidenced by the fact that federal duties of the FDA are placed at issue as a result of the allegations contained in plaintiffs' Complaint.

29. Further, proceeding with this case in federal court will not disturb "any congressionally approved balance of federal and state judicial

responsibilities." See id. at 314. The reason is that Congress's intent was clear with respect to Class III medical devices. See Riegel, 552 U.S. at 316, 326 (holding that the text of § 360k(a) clearly and expressly evinces Congress's intent to displace the tort law of 50 States and impose a regime of detailed federal oversight). Another reason is that claims concerning Class III PMA medical devices constitute a very small fraction of an already very small subset of medical devices. See 21 U.S.C. § 360c(a)(1)(C)(ii) (delineating that Class III devices are only those which support or sustain human life or present a potential unreasonable risk of illness or injury). Federal jurisdiction over the narrow class of cases is thus fully consistent with the "balance of federal and state judicial responsibilities" and the "congressional judgment about the sound division of labor between state and federal courts." Grable, 545 U.S. at 314-15.

30. Although it appears, after extensive research, that the Third Circuit has not decided this precise issue as it pertains to removal and Class III PMA medical devices, federal courts throughout our nation have approved and upheld federal-question jurisdiction and notices of removal on the same basis discussed supra. See H.R. v. Medtronic, Inc., 996 F. Supp. 2d 671 (S.D. Ohio 2014) (holding that the substantial-federal-question doctrine applied and thus federal jurisdiction existed); Arrington v. Medtronic, Inc., 130 F. Supp. 3d 1150 (W.D. Tenn. 2014); Dooley v. Medtronic, Inc., 39 F. Supp. 3d 973 (W.D. Tenn. 2014) (same); Jenkins

v. Medtronic, Inc., 984 F. Supp. 2d 873 (W.D. Tenn. 2013) (holding that such claims are properly subject to federal-question jurisdiction under the substantial-federal-question doctrine because they undoubtedly require a court to examine federal law, particularly federal requirements imposed by the FDA through the PMA process).

31. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. § 1331 and this case is removable under 28 U.S.C. § 1441.

ALTERNATIVELY, DIVERSITY JURISDICTION WILL EXIST AFTER SEVERANCE OF THE MEDICAL DEFENDANTS PURSUANT TO FED. R. CIV. P. 21

32. In the event that this Court does not find federal question jurisdiction, there will be diversity jurisdiction if this Court severs the Medical Defendants.

33. Fed. R. Civ. P. 21 provides that the court may at any time, on just terms, add or drop a party.

34. If this Honorable Court severs the Medical Defendants pursuant to Rule 21, diversity jurisdiction will exist between plaintiffs and Defendant Biotronik because (1) the suit will be between citizens of different states and (2) the amount in controversy exceeds $75,000, exclusive of costs and interest.

35. According to the Complaint, plaintiffs reside in Meshoppen, Susquehanna County, Pennsylvania, and thus are citizens of Pennsylvania. See Exhibit A, at ¶¶ 1-2.

36. Defendant Biotronik is a Delaware corporation with a principal place of business located at 6024 Jean Road, Lake Oswego, OR 97035.

37. According to the Complaint, the Medical Defendants are all citizens of Pennsylvania. See id. at ¶¶ 5-8.

38. As currently situated, the parties are not completely diverse because plaintiffs and the Medical Defendants are citizens of Pennsylvania.

39. Federal Rule of Civil Procedure 21 grants the Court discretion to retain jurisdiction by severing claims against nondiverse dispensable defendants. Newman-Green, Inc. v. Alfonzo-Larrain, 490 U.S. 826, 832 (1989).

40. The Medical Defendants are neither necessary nor indispensable, see Fed. R. Civ. P. 19, because resolution of the medical malpractice/state tort claims against them would not resolve the products liability claims against Biotronik, and vice versa. The claims against the Medical Defendants involve different legal standards and factual allegations than those asserted against Biotronik.

41. Further, as set forth supra, plaintiffs' claims against Biotronik involve allegations of violations of federal law, whereas the same cannot be said for the claims against the Medical Defendants.

42. Moreover, severing the Medical Defendants will not be unduly prejudicial because plaintiffs can proceed with their medical malpractice/state tort law claims against the Medical Defendants in State Court.

43. Accordingly, if the Court does not find federal question jurisdiction, the Court should sever the Medical Defendants and exercise jurisdiction over this action.

44. Should the Court sever the Medical Defendants, the amount in controversy would exceed $75,000 based on a fair reading of the Complaint, as the Complaint claims that plaintiff died as a result of product defects and other allegations arises under products liability claims. See 28 U.S.C. § 1332(a); see also Exhibit A.

WHEREFORE, Defendant, Biotronik, Inc., respectfully requests that this action be removed from the Court of Common Pleas for Lackawanna County, assigned for further proceedings to the United States District Court for the Middle District of Pennsylvania, and that this case be assigned to a Judge for proper disposition.

Respectfully submitted,

MARSHALL DENNEHEY
WARNER COLEMAN & GOGGIN

By: _____

Matthew P. Keris, Esquire
PA Attorney I.D. #78704
Robert J. Aldrich III, Esquire
PA Attorney I.D. #315911

P.O. Box 3118
Scranton, PA 18505-3118
(570) 496-4600
Counsel for Defendant, Biotronik, Inc.

CERTIFICATE OF SERVICE

I, Robert J. Aldrich III, Esquire, do hereby certify that a true and correct copy of the foregoing Notice of Removal was served upon all parties by first class mail on the 23rd day of June, 2016 at the following addresses:

Clifford A. Rieders, Esquire
Rieders, Travis, Humphrey, Waters & Dohrmann
161 West Third Street
Williamsport, PA 17701

Patrick C. Carey, Esquire
Cipriani & Werner, PC
409 Lackawanna Ave., Suite 402
Scranton, PA 18503

Respectfully submitted,

MARSHALL DENNEHEY
WARNER COLEMAN & GOGGIN

By: _____

Matthew P. Keris, Esquire
PA Attorney I.D. #78704
Robert J. Aldrich III, Esquire
PA Attorney I.D. #315911
P.O. Box 3118
Scranton, PA 18505-3118
(570) 496-4600
Counsel for Defendant, Biotronik, Inc.